The following remarks are submitted to supplement applicants' Request for Continued Examination and Suspension of Action filed on October 3, 2002 in response to the Examiner's Final Office Action of June 3, 2002.

REMARKS

Reconsideration of the patentability of applicants' claims is requested respectfully.

Status of the Claims

The Examiner's Action addresses all of applicants' elected claims, namely Claims 1, 3, 6, 7 and 27. No claims have been amended or cancelled. Claims 28 to 38 have been added. Accordingly, there is presented for the Examiner's consideration Claims 1, 3, 6, 7, 27, and 28 to 38.

The claims added by this amendment are supported by the specification as filed. Support for new claims 28, 29, 34 and 37 appears on page 5, first paragraph. Support for new claims 30, 31, 35, and 38 appears on page 5, second paragraph. Support for new claims 32, 33 and 36 appears on page 6, second paragraph.

Submitted herewith are two pages entitled "Revised Version with Markings to Show Claim Changes Made", in which the bracket indicating deletion of text in line 6 of Claim 1 has been moved to include the words "the backing layer" which were not included by the bracket in the "Copy with Markings to Show Changes Made" which accompanied applicants' Reply of October 15, 2001. This addresses the request for clarification issued by the Examiner in the Action of June 3, 2002.

Introduction and Summary of the Examiner's Rejections

In response to applicants' Reply of March 15, 2002 to the Action of October 15, 2001, the Examiner has asserted new rejections, declaring applicants' arguments in their previous Reply moot in view of the new rejections. The new rejections include the citation of three references not previously of record, one of which is the basis of the Examiner's §102 rejection. All of the newly cited references are relied upon in the §103 rejections.

Claims 1 and 27 have been rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent No. 6,165,497 to Osborne *et al.* (hereafter "the Osborne reference").

Claims 1, 3, 6, 7 and 27 have been rejected under 35 U.S.C. § 103 (a) as being obvious over the knowledge of one of ordinary skill in the art in combination with either:

(A) the disclosure of the aforementioned Osborne reference;

(B) the disclosure of U.S. Patent No. 5,603,947 to Wong *et al.* (hereafter "the Wong reference"); or

(C) the disclosure of U.S. Patent No. 5,298,257 to Bannon *et al.* (hereafter "the Bannon reference").

Claim 3 has been rejected also under 35 U.S.C. §103(a) as being obvious over the disclosure of any one of the Osborne, Bannon, or Wong references in view of U.S. Patent No. 5,316,759 to Rose *et al.* (hereafter "the Rose reference").

In addition, Claim 6 has been rejected under 35 U.S.C. §103(a) as being obvious over the disclosure of any one of the Osborne, Bannon, or Wong references in view of U.S. Patent No. 5,721,257 to Baker *et al.* (hereafter "the Baker reference").

Reconsideration of the Examiner's rejections is requested respectfully.

Summary of Applicants' Invention

Applicants' invention is summarized in the Reply that was filed on March 15, 2002. As reflected in applicants' Claims 1 and 27 and as described in detail in the March 15 Reply, two features which distinguish applicants' patch over the prior art are: (i) a solid silicone adhesive layer which contains a normally volatile drug (for example, nicotine) and which is a source in the patch of the drug; and (ii) a solid acrylic adhesive layer which underlies (viewed from the area of skin contact) the silicone adhesive layer and which is in diffusional contact therewith. The resins comprising these layers and the positioning of the layers in the patch are critical to the effective manufacture of the patch and to its successful functioning.

Volatile drug in the patch is contained in the layer of silicone adhesive, which unlike most adhesives, is highly soluble in a high vapor pressure solvent, for example, hexane. Such solubility properties of the silicone adhesive permit the use of a high vapor-pressure solvent which evaporates readily at a relatively low temperature, that is, at a temperature at which loss of the volatile drug is minimized or avoided during the drying process which results in the formation of the solid layer of the drug-containing silicone adhesive. In contrast, the use of an adhesive (as the drug-containing adhesive) which is not highly soluble in a high vapor-pressure solvent and which requires the use of a solvent that has a relatively low vapor pressure (thus, requiring the use of relatively high "evaporating" temperatures) would result in the loss of a substantial amount of the volatile drug during the manufacturing process. The acrylic of the adhesive layer underlying the silicon adhesive layer is chosen because the rate of drug diffusion through the acrylic adhesive is slower than the diffusion rate through a silicone adhesive. Accordingly, there is a controlled diffusion of the drug from the acrylic adhesive layer to the skin over a sustained period of time.

The discussion which follows shows clearly that none of the references of record discloses or renders obvious this combination of resin layers in a patch which contains

a volatile drug. The disclosures of the references cited by the Examiner in the rejections are set forth in summary form below.

Summary of the Disclosures of the References

The disclosure of each of the references first made of record in the Action of June 3, 2002 is summarized below. The disclosures of the references identified above as the Baker and Rose references are summarized in applicants' Reply of March 15, 2002 and are not repeated herein.

U.S. Patent No. 6,165,497 to Osborne *et al.*

The Osborne reference discloses a transdermal patch for the administration of nicotine comprising (col. 3, lines 30-55) the following essential elements: (a) a nicotine-containing layer which functions as a source in the patch of nicotine; (b) a nicotine flux rate-controlling layer; and (c) a skin-contacting adhesive layer (col. 4, lines 54-55).

The nicotine-containing layer described in the Osborne reference is a viscous mass which is capable of either "flowing or oozing" (col. 3, line 44) or which has "sufficient viscosity to maintain its structural integrity" (col. 3, line 46) and which comprises "... nicotine dissolved in a solvent..." (col. 4, lines 63-64) and nicotine admixed with "...natural and synthetic rubbers or other polymeric materials, thickened mineral oils or silicone fluids or petroleum jelly..." (col. 6, lines17-19). Preferably, the nicotine-containing layer of the Osborne patch comprises ethylene vinyl acetate (EVA) copolymer (col. 6, lines 21-22). The Osborne reference does not disclose the use of a silicone resin as an adhesive layer which contains nicotine and which is in solid form.

The nicotine flux rate-controlling layer described in the Osborne patch comprises either a "dense polymer film ...[permeable]... to nicotine" (col. 6, lines 31-32) or an oil-filled, microporous, drug-impermeable polymer membrane as described in U.S. Patent

Nos. 3,792,494 to Zaffaroni and 4,031,894 to Urquhart *et al.*, (col. 6, line 67 - col. 7, line 4). The Osborne reference does not disclose the use of an acrylic resin as the nicotine flux rate controlling layer.

The Osborne skin-contacting adhesive layer which underlies the rate-controlling layer is described as a material which is known in the art for use in a transdermal patch and through which nicotine can diffuse such that the adhesive "does not constitute a significant permeation barrier to the passage of nicotine" (col. 7, lines 5-15), for example, silicone-based adhesives such as, for example, Dow Corning X7-2920 (col. 7, lines 28-30).

In summary, the Osborne reference does not describe the combination of a solid silicone adhesive layer which is a source of the drug in the patch and, underlying and in diffusional contact therewith, a solid acrylic adhesive layer.

U.S. Patent No. 5,603,947 to Wong *et al.*

The Wong reference describes a transdermal patch which releases nicotine rapidly over a short time span and which does not have sustained release properties (col. 5, lines 29-35). The transdermal patch described in the Wong reference has a single layer, described therein as a "matrix", comprising a mixture of nicotine and an adhesive polymer in which nicotine exhibits a solubility of less than 30 wt.% (col. 3, lines 15-20 and col. 4, line 63 - col. 5, line 3) or, alternatively, a non-adhesive mixture of a polymer and nicotine which has underlying it a layer of a skin-contacting adhesive. The Wong reference further characterizes the adhesive used for construction of the matrix or for construction of the skin-contacting adhesive layer as not altering or affecting the release pattern of nicotine from the matrix (col. 6, lines 31-34). A suitable adhesive is exemplified by a silicone-based adhesive.

The Wong reference does not disclose the combination of a solid silicone adhesive layer which is a source of the drug in the patch and underlying and in diffusional contact therewith a solid acrylic adhesive layer.

U.S. Patent No. 5,298,257 to Bannon *et al.*

The Bannon reference discloses nicotine-containing compositions having a physical form ranging from a cream to a solid (col. 8, lines 11-36). The compositions comprise 0.5 - 25 wt.% nicotine and, when contacted with the skin, deliver nicotine transdermally in a manner in which ". . . the skin itself . . . forms the rate controlling barrier . . . not the dosage form comprising the [transdermal patch]" (col. 5, lines 39-43). The Bannon reference identifies a wide range of materials which can comprise the subject compositions, including a generic recitation of those which contain the silicon atom, for example, silicon dioxide and silicone polymers (col. 4, lines 20-23). The silicone polymer-containing compositions of the Bannon reference are exemplified in Example 3 which describes a patch having a nicotine-containing layer comprising a cured, non-adhesive silicone rubber.

The Bannon reference generically describes a nicotine-containing solid which may have a skin-contacting face comprising an adhesive layer which is "freely permeable to nicotine" (col. 7, lines 15-20). The Bannon reference does not further describe or exemplify the adhesive.

The Bannon reference does not disclose a transdermal patch comprising a solid silicone adhesive layer which is a source of the drug in the patch and, underlying and in diffusional contact therewith, a solid acrylic adhesive layer.

Discussion of the Examiner's Rejections

Each of the Examiner's § 102 and § 103 rejections is traversed respectfully.

The §102 Rejection Based on the Osborne Reference

The Osborne reference discloses neither a solid silicone adhesive layer which contains a drug and is a source of the drug in the patch nor a solid acrylic adhesive layer underlying and in diffusional contact therewith. The source of drug (nicotine) in the Osborne patch is not a solid silicone adhesive layer; the source is described therein as a "reservoir" which can comprise a viscous mass of nicotine dissolved in a solvent or admixed with natural or synthetic rubbers or other polymeric materials, thickened mineral oils or silicone fluids or petroleum jelly. Inasmuch as Osborne does not disclose the use of a solid silicone resin in a layer which functions also as a source of the drug, the Examiner's §102 rejection is without merit.

The §102 rejection is also without merit because applicants' claimed patch includes a solid acrylic adhesive layer which underlies and is in diffusional contact with the solid silicone adhesive layer of applicants' patch. The Osborne patch does not include a solid acrylic adhesive layer.

The Examiner has characterized the patch described in the Osborne reference as having a "vinyl acetate copolymer (acrylic adhesive) rate-controlling membrane," citing col. 7, lines 1-4 and 28-30 of the Osborne reference. Accordingly, the Examiner's §102 rejection is based on the erroneous position that the ethylene vinyl acetate copolymer rate-controlling membrane described in the Osborne reference is equivalent to the solid acrylic adhesive layer of applicants' patch.

Contrary to the position taken by the Examiner, it is well known that the aforementioned two resins are fundamentally different materials. Attached hereto is Appendix A which shows the structural differences between ethylene vinyl acetate copolymer and an acrylic resin.

None of the other resins disclosed by Osborne for use as the rate-controlling membrane is an acrylic resin. Note that the Osborne reference cites U.S. Patent Nos. 3,797,494 to Zaffaroni and 4,031,894 to Urquhart et. al. as disclosing resins for use as rate-controlling membranes. These patents describe porous membranes in which the membrane is made from inert, non-adhesive polymers such as polyethylene, which is impregnated with oil as a diffusion medium through which a drug diffuses to the site of administration. The Osborne reference does not disclose the use of an acrylic resin in any form for use in the patch described therein.

The Examiner has cited the disclosure in the Osborne reference at col. 7, lines 28-30 to support the Examiner's assertion that the Osborne reference discloses a reservoir comprising nicotine and a silicone adhesive. This section of the Osborne reference discloses that a skin-contacting adhesive layer underlying the rate-controlling layer of the Example 1 patch in the Osborne reference is constructed of a silicone adhesive. This skin-contacting silicone adhesive layer is not a source in the patch of nicotine, but merely a conduit for the flow of nicotine to the skin situs to which nicotine is to be administered. As explained above, the source of nicotine in the Osborne patch is a "reservoir" which overlies the rate-controlling layer (col. 3, lines 30 - 55) under which the adhesive layer described at col. 7, lines 28-30 is placed.

Inasmuch as applicants' claimed patch distinguishes over the patch of the Osborne reference in at least two respects, as explained above, it is requested respectfully that the Examiner's § 102 rejection be withdrawn.

The Examiner's obviousness rejections are addressed below.

The §103 Rejections Based on the Osborne Reference

The Examiner's §103(a) rejections of Claims 1, 3, 6, 7, and 27 which are based on Osborne are traversed. As explained above, the Osborne reference does not describe a patch which includes either a solid silicone adhesive layer that contains a drug and that

is a source of the drug in the patch nor a solid acrylic adhesive layer which underlies and is in diffusional contact therewith.

In the obviousness rejections based on the Osborne reference, the Examiner has not cited any evidence of the state of knowledge of one of ordinary skill in the art that would lead one to modify the patch described in the Osborne reference to yield applicants' patch, stating only that "it is well known in the art to treat addiction ... by administering the drug and its antagonist" and further that a "siliconized release liner is also well known in the art." Inasmuch as the Osborne patch and applicants' patch have materially different constructions and there is no teaching or even a remote suggestion respecting the modification of the Osborne patch to yield a patch of applicants' construction, it is requested respectfully that the Examiner's §103(a) rejections based on the disclosure of the Osborne reference be withdrawn.

The §103 Rejection of Claim 3 Based on the Osborne Reference in Combination With the Rose Reference and of Claim 6 Based On the Osborne Reference in Combination With the Baker Reference.

The Rose reference, summarized in applicants' Reply to the Office Action of October 15, 2001, discloses no single structural or functional feature that corresponds to a structural or functional feature of applicants' development. Summarizing from applicants' earlier Reply, the Rose reference discloses a transdermal patch having as a source of a drug either a liquid solution containing the drug or a liquid drug in a neat form, contained in a pouch formed between a liquid-impermeable backing layer and a liquid-permeable skin-contacting layer. The disclosure of the Rose reference when combined with the disclosure of the Osborne reference does not result in a patch having a solid silicone adhesive layer which contains a volatile drug and is a source of the drug in the patch nor a solid acrylic adhesive layer underlying and in diffusional contact with

the solid silicone adhesive layer. Accordingly, it is requested respectfully that the Examiner's §103 rejection of Claim 3 based in part on the Rose reference be withdrawn.

Similarly, as discussed in applicants' Reply of March 15, 2002, the Baker reference discloses a transdermal patch in which the source of a drug in the patch is a solid, non-adhesive acrylic layer which has underlying it a skin-contacting adhesive layer that may be a silicone-based adhesive. Thus, the Baker reference discloses a patch having an order of materials which is inverted from those of applicants' claimed patch. Accordingly, the combined disclosures of the Osborne and Baker references do not result in applicants' claimed patch and, thus, the §103 rejection of Claim 6 should be withdrawn.

The Examiner's § 103 rejections based on Wong and Bannon are addressed below. The discussion below shows that both the Wong and Bannon references fail to disclose all elements of applicants' patch and that the elements which these references fail to disclose are not supplied by the ordinary level of skill in the art, the Rose reference as regards Claim 3, or the Baker reference as regards Claim 6.

The §103 Rejections Based on the Wong Reference

The Wong reference does not disclose applicants' claimed patch in that applicants' claims recite the combination of a solid silicone adhesive layer which is a source of a drug in the patch and underlying and in diffusional contact therewith a solid acrylic adhesive layer. Furthermore, the Wong reference teaches away from modification of the patch disclosed therein to yield the patch of applicants' invention. As stated above in the summary of the Wong reference, Wong discloses, at col. 5, lines 29-35), that the advantages of the Wong patch are: (i) a rapid-release of nicotine; and (ii) it does not have sustained-release properties. The patch described in the Wong reference has a layer which is the source in the patch of the drug (nicotine), described therein as a "matrix", which is either: (A) an adhesive comprising a mixture of nicotine and an adhesive

polymer (which may be a silicone adhesive) in which the nicotine has a solubility of less than 30 wt.% (col. 3, lines 15-20, col. 4, line 63 - col. 5, line 3 and col. 5, lines 56-58); or (B) a non-adhesive comprising a mixture of a polymer and nicotine. When the matrix of the Wong patch is an adhesive, it is applied directly to the situs of nicotine delivery and when the matrix is non-adhesive, it has a layer of a skin-contacting adhesive underlying it. In either form the "matrix" layer may comprise a silicone adhesive. Except as discussed below, the composition of the optional skin-contacting adhesive, if used, is not described in the Wong reference, although it is preferred for any such adhesive to be of the same chemical class as the polymer comprising the matrix layer (col. 6, lines 32-34).

In the §103 rejection based on the Wong reference, the Examiner characterizes the reference as disclosing a transdermal delivery device comprising "a matrix layer containing nicotine and silicones ...[and] an adhesive layer to affix the device to the skin...". In support of this characterization, the Examiner cites the Wong reference at: (a) the abstract and col. 2, lines 16-20, (b) col. 3, lines 15-18; (c) col. 5, lines 51-53 (which lists polymers that may comprise the matrix layer, one of which may be a silicone-based polymer); (d) col. 6, lines 1-8 (which discloses that the matrix layer may be adhesive); and (e) col. 6, lines 40-45 (which describes the combination of a non-adhesive matrix layer and a skin-contacting adhesive layer).

Applicants note the Wong reference discloses at col. 5, lines 20-24, that the matrix layer, whether adhesive or not, is the element of the patch which regulates the delivery flux of the drug contained therein and further discloses at col. 6, lines 31-37, that the presence of a skin-contacting adhesive layer does "...not materially alter or affect the release pattern of nicotine..." from the patch.

The foregoing description in the Wong reference teaches away from any modification of the Wong patch which would result in a transdermal patch exhibiting either: (i) sustained-release characteristics; or (ii) the addition of one or more layers

which modify the release characteristics of the Wong matrix layer. As discussed in applicants' Reply of March 15, 2002, one of the features provided by the patch of applicants' invention is the provision of a patch having sustained-release properties. As also discussed in applicants' Reply of March 15, 2002, this is accomplished by applicants' use of a solid silicone adhesive layer (having a relatively fast rate of diffusion) in combination with a solid acrylic adhesive layer (having a relatively slow rate of diffusion). It is abundantly clear that the Wong reference teaches away explicitly from the modification of the patch disclosed in Wong in a manner which would result in applicants' patch that has properties specifically rejected by the disclosure of the Wong reference.

Accordingly, the Examiner is requested respectfully to withdraw the §103 rejection of all claims based on the disclosure of the Wong reference, whether in combination with the level of ordinary skill in the art or in combination with the Rose reference as applied to Claim 3, or in combination with the Baker reference as applied to Claim 6, for the reasons stated above.

The §103 Rejection Based on the Bannon Reference

As discussed above in the summary of the Bannon reference, applicants' claims distinguish over the disclosure of Bannon in defining a patch which includes a solid silicone adhesive layer that is a source in the patch of a drug and a solid acrylic adhesive layer underlying and in diffusional contact therewith.

The Bannon reference describes compositions which have a physical form that ranges from a cream to a solid and which contain nicotine and a silicone polymer and which, when contacted with the skin, administer nicotine transdermally at a rate controlled by the skin.

In formulating the § 103 rejection based on the Bannon reference, the Examiner has implied that Bannon's solid nicotine-and silicone-containing composition is the

equivalent of the solid silicone adhesive layer of applicants' patch. However, none of the solid nicotine-containing compositions described in the Bannon reference is adhesive. This is evidenced by Bannon's disclosure that the "Bannon" composition has a skin-contacting surface that is coated with an adhesive layer (col. 7, lines 39-43). The Examiner states further in the rejection that "it is known in the art to have a rate-controlling membrane in ...the patch". However, the Bannon reference teaches away from the combination of the "Bannon" composition and a rate-controlling membrane in that Bannon describes, as an aspect of the "Bannon" composition, that it supplies nicotine at a rate regulated by the skin to which the composition is applied (col. 5, lines 39-43)

Note that the aforementioned adhesive layer which is applied to the skin-contacting face of the "Bannon" composition is described as "freely permeable" to nicotine. In view of the fact that the Bannon reference characterizes the compositions described therein as supplying nicotine at a rate regulated by the skin to which they are applied (col. 5, lines 39-43), a "freely permeable" adhesive layer is not a layer which functions to regulate the flux of a drug delivered by the patch in which it is included. As set forth in applicants' Reply filed March 15, 2002, the solid acrylic adhesive layer in applicants' patch functions to regulate the flux delivered by the patch.

Accordingly, the Bannon reference discloses neither a solid silicone adhesive layer which contains a drug and which is a source of the drug in a patch nor a solid acrylic adhesive layer underlying and in diffusional contact therewith. The Bannon reference teaches away from a patch comprising such a combination of adhesive layers, as discussed above. Accordingly, it is requested respectfully that the § 103 rejections based on the disclosure of Bannon be withdrawn.

Also submitted herewith are 2 pages entitled "Version with Markings to Show Claim Changes Made", in which new claims 28 to 38 are shown underlined in their entirety to indicate that they are being added.

Respectfully submitted,

Synnestvedt & Lechner LLP

December 23, 2002
Date

H. Eric Fischer, Ph.D., Esquire
Registration No. 46,010

Synnestvedt & Lechner LLP
2600 ARAMARK Tower
1101 Market Street
Philadelphia, PA 19107-2950
(215) 923-4466

Revised Version With Markings To Show Claim Changes Made

1. (Once Amended) A transdermal patch for administering a volatile liquid drug transdermally to a patient comprising:

a) a top backing layer that is impermeable to the drug;

b) an intermediate solid silicone adhesive layer which underlies the backing layer, which contains the drug and is a source in the patch of the drug [containing the drug and underlying the backing layer];

c) [an] a solid acrylic adhesive layer [also containing the drug that] which underlies and is in diffusional contact with the silicone adhesive layer; and

d) a removable release liner layer underlying the acrylic adhesive layer,

wherein the [combined] amount of drug in the patch [silicone adhesive layer and acrylic adhesive layer] is sufficient to provide a therapeutically effective amount of drug to the patient.

27. (New Claim) A transdermal patch for administering volatile liquid drugs transdermally comprising:

a) a top backing layer that is impermeable to the drug;

b) a cast pressure-sensitive silicone adhesive layer which is contiguous to and underlies the backing layer, which contains said drug, and which is a source of the drug for the patch;

c) a solid pressure-sensitive acrylic adhesive layer which is contiguous to and which underlies and is in diffusional contact with said silicone adhesive layer; and

d) a removable release liner underlying the acrylic adhesive layer;

wherein the amount of drug in the patch is sufficient to provide a therapeutically effective amount of drug to the patient.

Copy To Show Changes Made

28. (New Claim) The patch of Claim 1, wherein the silicone adhesive layer comprises a silicone pressure sensitive adhesive.

29. (New Claim) The patch of Claim 28, wherein the silicone adhesive layer is about 25 to about 100 microns thick.

30. (New Claim) The patch of Claim 28, wherein the acrylic adhesive layer comprises an acrylic pressure sensitive adhesive.

31. (New Claim) The patch of Claim 30, wherein the acrylic adhesive layer is about 25 to about 100 microns thick.

32. (New Claim) The patch of Claim 27, wherein the drug comprises a mixture of nicotine and mecamylamine.

33. (New Claim) The patch of Claim 28, wherein the drug comprises a mixture of nicotine and mecamylamine.

34. (New Claim) The patch of Claim 27, wherein, the silicone adhesive layer in its initially cast form contains between about 5 wt % and about 50 wt. % of the drug based on the total dry weight of the drug and adhesive.

35. (New Claim) The patch of Claim 27, wherein said acrylic layer comprises about 2.5 wt. % to about 30 wt. % of the drug after equilibration.

36. (New Claim) The patch of Claim 3, wherein the patch contains an amount of drug sufficient to provide administration of the drug for a period of up to about 72 hours.

37. (New Claim) The patch of Claim 34, wherein the silicone layer contains 10 to 30 wt. % of the drug.

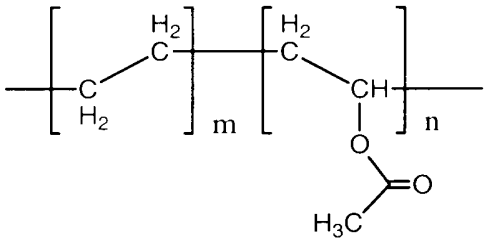
38. (New Claim) The patch of Claim 7, wherein the acrylic adhesives comprise a copolymer which is the polymerization product of a blend of monomers of which at least 50 wt. % are selected from the group consisting of 2-ethylhexyl acrylate, butylacrylate, and iso-octyl acrylate.

M:\EFischer\Elan Corp plc\P-24540.usa\Patent Office\draft 5 -- revised reply to final OA of 6-3-02.wpd

Appendix Summarizing Structural Differences

Between Acrylate and Ethyl Vinyl Acetate Copolymer

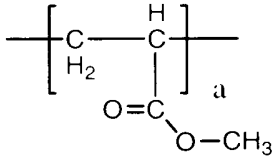
As mentioned above, the patch of the Osborne reference contains a "rate controlling membrane" that is described in detail beginning at Col. 6, line 31. The Osborne reference discloses that the membrane may comprise an ethylene vinyl acetate copolymer (Col 7, line 4, and elsewhere in the examples). As discussed above, the ethylene vinyl acetate copolymer membrane thus described has been erroneously characterized by the Examiner as being the equivalent of a solid acrylic adhesive layer. Ethylene vinyl acetate copolymers are known in the art to have a structure shown in Structure I:



Structure I

with random values of "m" and "n" appearing along a polymer chain.

Acrylate polymers, which are a component of acrylate pressure sensitive adhesives such as those used in the acrylic adhesive layer underlying the silicone adhesive layer of applicants' patch, have the characteristic structural feature show in Structure II:



Structure II

Appendix A
(1)

where "a" designates a polymeric number of repeating units. The two materials are known to have different chemical and physical properties, including that ethylene vinyl acetate copolymer is in general not adhesive.

M:\EFischer\Elan Corp plc\P-24540.usa\Patent Office\Appendix I - acrylate vs acetate structure.wpd